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14. ABSTRACT
The primary goal of this proposal is to conduct a pilot study for the legally mandated statewide population-based PD registry. This is one of two linked proposals, submitted by the University of California-Los Angeles (UCLA) and the Parkinson's Institute. For this proposal by UCLA, the work funded is being conducted in Kern, Tulare and Fresno counties. Thus far a total of 2,741 PD cases in these three counties have been identified from legally mandated sources (health care institutions, physicians and other providers). A secure prototype database has been established. Exploratory investigations will be conducted on the association between PD and toxicant chemical exposure by linking to a database of toxicant chemicals established previously by UCLA based on California state data (e.g. the pesticide use databases). Differences in patterns of PD care will be assessed among groups defined by age, gender, place of residence and, as possible, socioeconomic status and race/ethnicity.

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California Parkinson's Disease Registry Pilot Project – Southern California Ascertainment

Annual Report, 01 Mar 2009 – 28 Feb 2010

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Introduction

The primary goal of this research is to conduct a pilot study for the legally mandated statewide population-based Parkinson's diseases (PD) registry in California. This study is one of two linked research programs with the goal of establishing and using the California PD registry data, i.e. a concerted effort by both the University of California-Los Angeles (UCLA) and the Parkinson's Institute (TPI) in Sunnyvale, CA. The UCLA group was funded to and is currently conducting registry field work in Kern, Tulare, and Fresno Counties; TPI group was funded and is currently conducting field work in Santa Clara County, and was also funded to set up, and coordinate the field efforts of both groups including the establishment and maintenance of a secure data enclave for storage of this sensitive medical data. So far a total of 2,741 records for PD cases in the three counties (and an additional 4,949 PD cases in Santa Clara) have been identified from legally mandated sources (health care institutions, physicians and other providers); (note, these numbers do not yet account for duplicate records for the same patient received from different sources). A secure prototype database has been established at TPI for the data from both the UCLA and TPI field efforts. Currently efforts are underway to error check and de-duplicate the data we collected. Once this has been accomplished exploratory investigations will be conducted concerning associations between PD and toxicant chemical exposure by linking to a database of toxicant chemicals established previously by UCLA for California state data (e.g. the pesticide use databases). Differences in patterns of PD care will be assessed among groups defined by age, gender, place of residence and, as possible, socioeconomic status and race/ethnicity.

Body: Progress Report

The goals of this research are to conduct 1) a pilot study for the legally mandated California statewide population-based PD registry, 2) explore association between PD and toxicant chemical exposure by linking to a database of toxicant chemicals established previously by UCLA, and 3) to assess differences in patterns of PD care among groups defined by age, gender, place of residence and, as possible, socioeconomic status and race/ethnicity. The UCLA study is closely linked to a similar research effort at the Parkinson's Institute (TPI) in Sunnyvale California also funded by DoD. Specifically, TPI has been allocated the necessary funds to initiate and administer some primary registry efforts that include 1) setting up and conducting meetings with stakeholders, 2) obtaining approval from both the state institutional review board for human subject research and deputization by the California State Health Agency; 3) informing physicians and other entities that maintain records of PD patients of the upcoming registry data collection effort; and 4) error checking and de-duplicating all patient records and maintaining a secure registry database. After the initial preparatory work of obtaining the necessary approvals and informing all parties targeted by the data collection efforts had been completed, we began the pilot field work funded at both UCLA and TPI i.e. our actual data collection efforts. Some final data collection efforts are still in progress but we expect to be finishing these later this year.

The UCLA team has 1) participated regularly in the CA PD Project working group meetings and all conference calls involving preparatory planning efforts; and 2) also prepared applications for institutional review boards for the CA state committee and at UCLA. Furthermore, the UCLA team has conducted the majority of its field project phase and is currently in the process of wrapping up all data collection efforts. The TPI and UCLA have recently submitted a proposal

to the California Committee for the Protection of Human Subjects to conduct research with the surveillance data collected thus far; UCLA is now waiting for an approval of this IRB application and for TPI to finish the data error and duplicate checking to begin research analysis.

Three years ago, a stakeholders' meeting was convened by TPI in which UCLA (Dr. Ritz) participated. A year later we achieved formal deputization of the Parkinson's Institute and UCLA by the California Department of Health Services (note: as of July 2007, now the California Department of Public Health, CDPH). Last year, the health surveillance activities of the Pilot Registry (i.e. establishment of Registry methods and database, as specified in the CDPH contract) received a review waiver by the California Committee for the Protection of Human Subjects as well as by the institutional review boards of the investigators (The Parkinson's Institute, UCLA and Kaiser Permanente) and our funder (DoD). Since then the researchers at both institutions collaborated to develop confidentiality procedures for data collection, specifically data access and confidentiality policies and procedures for research meeting the specifications required by the CDPH contracts. These procedures are similar to and modeled onto existing protocols established for the California Cancer Registry (CCR) (http://www.ccrcal.org/PDF/CCRfacilityAccessPolicy-100206-v04-3.pdf). As in the CCR policies, the PD Pilot Registry policy defines the criteria, training and practices required to permit access/disclosure of any Pilot Registry data for health surveillance or research purposes.

Since the California PD Registry Act requires that formal notification of project launch be provided to the state medical and pharmacy boards as well as professional organizations representing physicians, pharmacists and health care institutions, a notification letter was prepared and mailed at the beginning of our field efforts. Also, letters and fact sheets announcing the Registry Pilot Project were released to health care professionals and the public by the TPI and UCLA. Further avenues for outreach are discussed by the Project working group and chair of the Stakeholders' Advisory Committee. Project leaders at CDPH, The Parkinson's Institute and UCLA have identified four California counties as designated reporting zones: Fresno, Tulare, Kern and Santa Clara. (Santa Clara was elected instead of the earlier provisional choice of Alameda County, as it offers population diversity and case finding opportunities which better complement those of the southern counties) and a Case Reporting Form has been developed by The Parkinson's Institute. The form includes fields for collection of data on basic demographics, key clinical parameters, and characterization of data collection feasibility. TPI and UCLA mainly conducted case finding via patient records available in neurologists' offices. This has permitted a preliminary assessment of data collection efficiency and challenges; if necessary, case finding may eventually be expanded to other sources such as institutional pharmacy records and data from hospital/residential care facilities furnished by the California Office of Statewide Health Planning and Development, and non-neurologist physicians.

In the past year, TPI and UCLA have also 1) applied for and have been approved to access Medicare data to allow us to conduct capture – recapture analyses and validate the data collection procedures im plemented for the regist ry in the past year; 2) applied for and are awaiting approval from the California State Co mmittee for the Protection of Hum an Subjects (CPHS) to explore association between PD and toxicant chem ical exposure by linking to a database of toxicant chem icals established pr eviously by UCLA and 3) applied for and are awaiting approval from the CPHS to assess di fferences in patterns of PD care am ong groups

defined by age, gender, place of residence and, as possible, socioeconomic status and race/ethnicity. To achieve this, TPI and UCLA submitted a joint proposal to the California State CPHS to conduct this research in the coming year with the data collected.

Case ascertainment from Parkinson's Disease health care providers. An important component of PD surveillance is to maintain a willingness of the Parkinson's Disease health care providers to cooperate with the mandate to report Parkinson's disease patients to the registry. Thus, our first method of case ascertainment was to approach and get collaboration from physician offices and medical groups that we expected to yield the greatest number of Parkinson's patients. The accomplishments including this past year, March 1, 2009 to February 28, 2010 are shown in the *Reportable Outcomes* section of this report. The tables show the number of patient records reported to us for whom we collected basic demographic and disease related information (note that these records have not been checked for duplicate reports).

We collected only a limited number of demographic variables for all patients, but have expand this effort to collect more detailed clinical information in a subset of patients, that will allow us to examine the validity of the PD diagnoses.

Staff Training in Data Collection. TPI and UCLA staff members working on registry data collection were trained in person at the TPI on September 4, 2009, September 5, 2009 and October 14, 2009. Since then there have been a two day in person training for a new UCLA staff member on June 11, 2009 and June 12, 2009. There have also been additional phone reviews and training session for the collection of more detailed clinical information in a subset of patients as established by the Scientific Advisory Committee. TPI and UCLA staff members were trained in person at the TPI on June 18, 2009, and there were several follow up trainings conducted by conference call.

In addition, weekly conference calls between TPI and UCLA staff members and principle investigators have continued to keep all employees updated on progress and the latest standard operating procedures.

Development of Registry Protocols and Design. The TPI developed most of the standard operating procedures. In the past year, the methods for conducting the detailed clinical information in a subset of patients were established by the Scientific Advisory Committee to examine the validity of the PD diagnoses. In this pilot phase of the registry, the TPI and UCLA are reviewing these procedures critically; update procedures and monitor progress ensure we are using the best methods for reaching the goals of this research. Secure databases have been developed by the TPI and are being used now during active cases ascertainment.

Project Advisor Committee. The TPI and UCLA have continued to reported progress to other CPDR Working Group members by conference call. An informal meeting on May 21, 2009 and a call with the entire working group was held on October 8, 2009. They will continue to meet by conference call over the next year. The next meeting is scheduled for March 9, 2010. TPI and UCLA have also collaborated through conference call meetings as part of the CPDR Scientific Advisory Committee.

Educational Program on the Protection of Human Subject Research. The TPI and UCLA continue to ensure that all staff employed in the project completed the appropriate security training and certification as required. This includes, human subject training, HIPAA training, Review of the CPDR Data Access & Disclosure Policy, Review of the CPDR Information Security Policy, and the CPDR Employee Confidentiality Pledge. In the past year additional training was added through the Collaborative Institutional Training Initiative (CITI) to enhance the assurance of patient confidentiality and proper data collection and storage.

Next Steps Planned

1) Continue to collaborate with TPI in improve training materials for medical records abstractors
2) Continue collecting basic demographic and disease related information for all cases of PD reported
3) Continue collecting more detailed clinical information in a subset of patients, that will allow us to examine the validity of the PD diagnoses
4) Collaborate with TPI in preparing data for analysis by identifying duplicate cases obtained from reporting sources
5) Collaborate with TPI in conducting capture – recapture analysis with Medicare data
6) Begin research upon approval of proposal to CA and UCLA IRBs for the research parts of our study which includes:
    i. Explore association between PD and toxicant chemical exposure by linking to a database of toxicant chemicals established previously by UCLA
    ii. Assess differences in patterns of PD care among groups defined by age, gender, place of residence and, as possible, socioeconomic status and race/ethnicity

Key Research Accomplishments

1) Completed contact lists for initial phase data sources
2) Collaborated with TPI in establishing secure database and data collection/transmission/storage procedures
3) Finalized data access and confidentiality procedures (including CDPH approval)
4) Collected basic demographic and disease related information for 2,741 PD case records in Kern, Tulare, and Fresno Counties
5) Collected more detailed clinical information for 87 PD cases in Kern, Tulare, and Fresno Counties to examine the validity of the PD diagnoses
6) Collaborated with TPI in maintaining outreach and information for all parties affected by the reporting requirements of the PD registry
7) Collaborated with TPI in maintaining contact with the County Health Officials in Santa Clara, Fresno, Kern, and Tulare Counties to inform them of the registry pilot project.
8) Received approval to use Medicare data to conduct capture – recapture analyses and validate the data collection procedures

Reportable Outcomes

Number of PD Patients for whom information was abstracted 01 Mar 2008 – 28 Feb 2010

	Northern CA Ascertainment (TPI)	Southern CA Ascertainment (UCLA)		
County	Santa Clara	Fresno	Kern	Tulare
N Total Pop N Pop 65+ age	1,764,499 192,330	909,153 90,006	800,458 72,041	426,276 40,922
Physician Offices Contacted	31	20	12	15
Medical Groups Contacted	8	0	4	2
# of Patient Records Reported	4,949	1,124	1,249	368
Total # of Patient Records Reported	4, 949	2,741		

Conclusions

After applying for and receiving all necessary approvals/ waivers from CA state and institutional (UCLA and TPI) agencies (e.g. human subject review boards) and conducting the necessary outreach efforts to stakeholders, the field efforts of this pilot study for the legally mandated California statewide population-based PD registry has been successful and a large number of patient data have already been collected (see above). Next we will explore the validity of our case ascertainment through capture recapture research analyses and also conduct some preliminary analysis to explore association between PD and toxicant chemical exposure and assess differences in patterns of PD care.

References

N/A

Appendices

None